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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,781	08/27/2003	Youssef Bennani	ATI-0025	4487

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EXAMINER

HUANG, EVELYN MEI

ART UNIT PAPER NUMBER

1625

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM-

Office Action Summary

Application No.

10/648,781

Applicant(s)

BENNANI ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 121-136 is/are pending in the application.
- 4a) Of the above claim(s) 121-136 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-15, 121-136 are pending. Claims 16-120 have been canceled according to the amendment filed on 7-9-2004.

Election/Restrictions

2. Newly submitted claims 121-136 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, drawn to a compound, classified in class 546, subclass 90.
- II. Claims 121-125, drawn to a process of making the compound.
- III. Claims 126-130, drawn to an alternative process of making the compound.
- IV. Claims 131-135, drawn to an alternative process of making the compound.
- V. Claim 136, drawn to an alternative process of making the compound.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product compound as claimed can be made by different materially different processes as described in the specification.

Since applicant has elected the invention of Group I in reply to the restriction requirement mailed on 6-9-2004, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 121-136 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Duplicate Claims

3. Claim 2 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. Claim 6 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 4. Claim 7 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 5. In view of the deletion of formula (i) in the definition of A in the amended claim 1, claims 2 and 1, 6 and 4, 7 and 5 are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1,

- Definition of G1-G4, K, the term 'acyl' is incomplete in that the substituents on the carbonyl are not described. The definition of acyl on page 20 should be recited in the claim.
- What are the 'suitable substituents' on the alkyl, aryl, heteroaryl etc. ? These substituents should be positively recited in the claim.
- In the last sentence before the proviso, it is unclear what is 'a combination of two or more thereof'. Does applicant intend to claim a combination mixture of the compound, a salt, a solvate, etc.?

The rejection is applicable to claims dependent on claim 1.

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Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 9, 15 rejected under 35 U.S.C. 102(b) as being anticipated by Griffith et al (Bioorganic & Medicinal Chemistry Letters. 2002, 12 (4); 539-542). Compound 12 (page 541) and the pharmaceutical composition thereof, are encompassed by the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 9, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joshi I (6376516, issued on 4-23-2002, is available as prior art under 102(b), PTO-1449, and is the US equivalent of WO 99/08528) or Joshi II (6673814, which is a CIP of 6376516) or Joshi (WO 99/08528, PTO-1449). The following reference made to 6376516 is therefore applicable to 6673814 and WO 99/08528)

Joshi I generically discloses an anti-neoplastic dioxolo[4,5-g]isoquinoline compound and the composition thereof (column 3; columns 21-22, claims 5-6). Examples 2-8 are described.

In Joshi's example compounds, C and D together form a 5-membered lactam ring. In the instant, D and C (corresponding to the instant E) does not form a ring.

Joshi, however, teaches that the formation of a ring is an optional choice (column 3, definitions of C and D; columns 21-22, claims 5, 6).

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At the time of the invention, one of ordinary skill in the art would be motivated to modify Joshi's example compound by making the alternative compound wherein C and D does not form a ring as taught by Joshi to arrive at the instant invention, with the reasonable expectation of obtaining an additional neoplastic agent since Joshi had clearly taught that any species within the disclosed genus would be useful for treating a neoplastic disease.

7. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umezu (EP 201359, PTO-1449)

Umezu generically discloses a phthalide isoquinoline compound and the composition thereof for inhibiting the formation of lipid peroxides (page 10). Examples are described (page 15).

The last compound of page 18 has a =O on the benzofuranyl. The compound of instant claims 4, 6 has a =S on the benzofuranyl.

Umezu, however, teaches that the =O and =S are optional choices (page 10, definition of Y). An example of =S is found on page 18, second compound.

At the time of the invention, one of ordinary skill in the art would be motivated to modify Joshi's example compound by replacing =O with the alternative =S to arrive at the instant invention, with the reasonable expectation of obtaining an additional lipid peroxide formation inhibiting compound, since Umezu had clearly taught that any species within the small disclosed genus would be useful for inhibiting the formation of lipid peroxides.

The last compound of page 18 has an ethoxy on the benzene ring of the benzofuranyl. The instant compound has a halo or alkyl instead.

Umezu, however, teaches that halo, alkyl or alkoxy (such as ethoxy) are optional choices (page 10, definitions R1-R9). An example of the bromo substituent is found on page 17, third compound.

At the time of the invention, one of ordinary skill in the art would be motivated to modify Joshi's example compound by replacing the ethoxy with the alternative bromo to arrive at the instant invention, with the reasonable expectation of obtaining an additional lipid peroxide formation inhibiting compound, since Umezu had clearly taught that any species within the small disclosed genus would be useful for inhibiting the formation of lipid peroxides.

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Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 9, 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-6 of U.S. Patent No. 6376516 or claims 1-17 of US Patent No. 6673814. Although the conflicting claims are not identical, they are not they are not patentably distinct from each other.

The anit-neoplastic compound wherein C and D do not a ring in the patented composition of 6376516 has a hydroxy as F is hydroxy whereas the instant has a methoxy as F. However, hydroxy and methoxy are optional choices (claim 1, definition of F). One of ordinary skill in the art would be motivated to replace the hydroxy with the alternative methoxy to arrive at the instant compound and the composition thereof.

The compound wherein C and D do not a ring in the composition of the patented delivery system of 6673814 is encompassed by the instant claims. One of ordinary skill in the art would be motivated to select the compound wherein C and D do not form a ring to arrive at the instant invention any species within the claimed genus would be useful for the treatment of a neoplastic disease.

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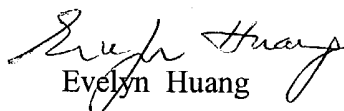
Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Evelyn Huang

Primary Examiner

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